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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:
April 2, 2001

Submitter:
GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:
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Sr. Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
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Device: Trade Name:
TRAM 2001 Module

Common/Usual Name:
Physiological Patient Monitor (Multi-parameter Module)

Classification Names:
Physiological Patient Monitor

Predicate Devices:
K921669 Marquette SL Series Transport Remote Acquisition Module (TRAM)

Device Description:
The TRAM 2001 Module is part of a multi-parameter modular system that measures and processes a patient's physiologic parameters. The TRAM 2001 Module works as a component of GE Medical Systems *Information Technologies* host monitoring systems and does not function on its own. The TRAM 2001 Module collects a patient's physiological data and sends it to a GEMS IT bedside monitor for display. TRAM modules incorporate different monitoring capabilities based on their configuration.

The TRAM 2001 Module can also be used as a transport monitor when used with the Transport Remote Acquisition Module Patient Monitoring System.

Intended Use:
The TRAM 2001 Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The TRAM 2001 Module is intended to provide uninterrupted monitoring of physiologic parameter data on adult, pediatric and neonatal patients during transport from one area of the hospital or facility, and monitoring system, to another. During non-transport monitoring, the TRAM 2001 Module functions in the bedside monitoring system.

Physiological parameter data includes ECG, invasive blood pressure, non-invasive blood pressure, pulse oximetry, cardiac output, temperature, and respiration. The TRAM 2001 Module acquires, processes and stores information regarding these parameters.

The device is intended for use in a professional medical facility, such as hospital, clinic, surgical center or doctor's office. The TRAM System can be used in multiple areas such as operating room (OR), post anesthesia recovery (PARR), critical care, surgical intensive care,

respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. The device is intended for use as part of a transport monitoring system for intra-hospital transport.

Technology:

The TRAM 2001 Module employs the same functional scientific technology as its predicate devices.

Test Summary:

The TRAM 2001 Module and its host patient monitoring system comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the TRAM 2001 Module:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing
- Clinical use validation

Conclusion:

The results of these measurements demonstrated that the TRAM 2001 Module are as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2001

Ms. Karen M. Webb
Senior Regulatory Affairs Specialist
GE Medical Systems
Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K011000
Trade Name: Tram 2000 Module
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: MHX
Dated: April 2, 2001
Received: April 3, 2001

Dear Ms. Webb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown; 510(k) filed on April 2, 2001

Device Name: TRAM 2001 Module

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011007

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)